REMARKS

The Official Action is a Restriction Requirement in which the Examiner urges that there are four separate and distinct inventions in the application. Applicants elect the Group II invention, without traverse. The claims directed to the non-elected invention have been canceled from the application subject to the right to file a divisional application thereto.

More particularly, claims 1-3 and 19 have been amended in accordance with the restriction requirement. Claims 9-12 and 26-27 have been canceled from the application without prejudice or disclaimer and subject to the right to file a divisional application including these claims. The claims now remaining in the application are claims 1-8 and 13-25. Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

Claim 1 has been amended by adding the restrictions from claim 9 into claim 1 and claim 9 has been canceled. Claim 2 has been amended for clarity and consistency with amended claim 1. Claim 3 has been amended to delete the multiple dependent claim and has been properly made dependent upon claim 1. Claim 19 has been amended to correct a typographical error.

Applicants are also submitting herewith two sheets of corrected formal drawings. Early notification of acceptance of the formal drawings are most respectfully requested.

In addition, a Supplemental Information Disclosure Statement with copies of the citations from the International Search Report and a full copy of "Quadros", cited previously in abstract only are being submitted herewith for consideration by the Examiner in the examination of this application on the merits. Also, several other relevant citations from the parallel direct U.S. application serial number 09/417,266 are included for the Examiner's review. It is most respectfully requested that the information cited herein be considered and entered into the application and acknowledged in the next Official Action.

In view of the above comments, further amendments to the claims and the election of the Group II invention without traverse, an early action on the merits is in order and most respectfully requested.

Respectfully submitted,

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Marked-Up Version of Changes Made

IN THE CLAIMS:

Please replace claims 1-3 and 19 with the following amended claims.

1(Amended). An assay method for the determination of transcobalamin II (TC II) bound cobalamin in a body sample, comprising contacting a cell free sample of a body fluid with an immobilized cobalamin or an analogue or fragment thereof which selectively binds the apo-forms of TC II and haptocorrin, and subsequently contacting said sample with an immobilised or immobilizable specific binding ligand for TC II or cobalamin bound TC II (holo TC II), separating a ligand bound fraction from a non-ligand bound fraction and measuring the holo-TC II or TC II bound cobalamin content therein.

2(Amended). An assay method as claimed in claim 1 wherein [said specific binding ligands for TC II or holo-TCII allow for separation and] the separation of said ligand bound fraction from said non-ligand bound fraction is so performed that the holo-TC II concentration [of the TC II or holo TC II in the sample of] is increased by at least 3-fold [and up to greater than 10-fold].

3(Amended). An assay method as claimed in claim 1 [or claim 2] wherein said assay is capable of detecting holo-TC II at a concentration as low as 9 pM.

19(Twice Amended). An assay method as claimed in claim 1 wherein said [holo=TC] holo-TC II containing sample is contacted with labelled holo-TC II and immobilised ligand therefor; said labelled and non-labelled holo-TC II complexes compete for binding to the immobilised ligand and after equilibrium is reached, the amount of labelled holo-TC II bound to the immobilised ligand is indirectly proportional to the amount of holo-TC II in the sample.